**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

TERESA L. STEVENS,

Plaintiff,

v. CIVIL ACTION NO. 2:16-cv-00265

BOSTON SCIENTIFIC CORPORATION, et al.,

Defendants.

**MEMORANDUM OPINION AND ORDER**

Pending before the court is the plaintiff's Class Action Complaint [ECF No. 1] ("Complaint") and Motion for a Preliminary Injunction [ECF No. 4]. For the reasons detailed below, the court applies the doctrine of primary jurisdiction to this matter and **REFERS** the issues discussed herein to the United States Food and Drug Administration ("FDA") for initial consideration of the allegations contained in the plaintiff's Complaint and Motion.

## I. Procedural History and Background

The plaintiff filed the Complaint on January 12, 2016, against Boston Scientific Corporation ("Boston Scientific") and other entities and alleges various claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), West Virginia Consumer Credit and Protection Act,[1] and West Virginia common law. Also on January 12, 2016, the plaintiff filed a Motion for a Temporary Restraining Order and a Preliminary Injunction. On January 13,

[1] The plaintiff cites to "W. Va. Code § 41A-6-103" in the fourth count of the Complaint; however, such a statutory section does not exist, nor does "Chapter 41A" exist within the West Virginia Code. The court will assume for the purpose of this Order only that the plaintiff intended to refer to the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-6-101, *et seq*.

2016, the court entered an Order [ECF No. 14] denying the plaintiff's Motion for a Temporary Restraining Order. The plaintiff filed a Motion for Expedited Hearing on Preliminary Injunction and Request to Shorten Time for Any Opposition [ECF No. 16]. On January 15, 2016, the court entered an Order [ECF No. 20] setting a briefing schedule regarding the plaintiff's Motion for Expedited Hearing. On January 19, 2016, the court entered an Order [ECF No. 26] requiring the parties to brief the applicability of the doctrine of primary jurisdiction to this case by noon on January 20, 2016. The parties filed briefs, and the court now considers the matter.

While the factual allegations made by the plaintiff against Boston Scientific are numerous, the court will review only those allegations relevant to the application of the doctrine of primary jurisdiction.[2] The plaintiff filed this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of herself and a putative class of similarly situated individuals who were implanted with Boston Scientific's transvaginal mesh products after September 2012. Compl. ¶ 1.

Boston Scientific manufactures and markets transvaginal mesh, which is a permanently implantable medical device. Compl. ¶ 10. According to the plaintiff, each year approximately 55,000 women receive a Boston Scientific mesh implant. *Id*. Advantage mesh, which Boston Scientific uses for all of its transvaginal mesh products, is subject to regulation by the FDA. *Id*. The plaintiff alleges Advantage mesh is made from Marlex HGX-030-1 ("Marlex"), a specific and unique polypropylene, and the device was cleared by the FDA under its 510(k) clearance process for medical devices. *Id*. The plaintiff alleges that, if Boston Scientific used anything

[2] It is readily apparent that the documents and factual allegations upon which the plaintiff relies may well be of importance in the multidistrict cases against Boston Scientific.

other than Marlex to form its mesh, "the product would not be Advantage mesh, as approved by the FDA." *Id.*

Marlex is manufactured in pellet form by a joint venture between the Chevron Corporation and Phillips Sumika Polypropylene Company ("Phillips") in LaPorte, Texas. Compl. ¶ 10. The plaintiff alleges Phillips decided to discontinue selling Marlex to Boston Scientific, so Boston Scientific began to run out of Marlex in 2011. *Id.* ¶ 11. According to the plaintiff, Boston Scientific resorted to smuggling counterfeit Marlex pellets out of China, into Belgium and, ultimately, into the United States in an effort to obtain the necessary material. *Id.* Allegedly, this "smuggling" occurred from June 2011 through the fall of 2012. *Id.*

The plaintiff alleges that she and the putative class members were permanently implanted with a counterfeit, adulterated product that was not approved by the FDA under Boston Scientific's original 510(k) application and clearance. *Id.* ¶¶ 15, 18. The plaintiff also alleges that Boston Scientific believed the FDA would likely not clear the use of a mesh made of material other than Marlex under its original 510(k) clearance. *Id.* ¶ 24. Further, the plaintiff alleges serious safety concerns surround this "counterfeit" Marlex resin because little is known of its provenance and testing. *See id.* ¶¶ 59–67.

The plaintiff emphasizes the potential seriousness of the safety concerns associated with the possibility that medical devices manufactured by Boston Scientific contain harmful, adulterated, and counterfeit resin in her Motion for a Temporary Restraining Order and a Preliminary Injunction. In the Motion, the plaintiff largely repeats many of the factual allegations contained in the Complaint. *See* Pl.'s Mot. TRO & Prelim. Inj. The plaintiff argues she and the putative class members all over the country need to make informed decisions about whether to

have mesh implanted or have the device removed and that such personal, medical decisions directly relate to their continued safety. Pl.'s Mem. Supp. Mot. TRO & Prelim. Inj. ¶ 72 [ECF No. 6]. The plaintiff claims the alleged counterfeit mesh "is not some defective headlamp on a Ford pickup. . . . This Counterfeit Product, smuggled by Boston Scientific out of China from a known counterfeiter, is a medical device (subject to FDA regulation) that is permanently implanted into the most intimate part of a woman's body." *Id*. ¶ 74. Further, the plaintiff alleges "[t]here is no doubt that the public health is at issue here." *Id*. ¶ 75. Finally, the plaintiff alleges "[t]he FDA, too, deserves to know the true history behind Boston Scientific's Counterfeit Product, and how it came into the United States without certificates of authenticity, proper provenance, or adequate testing." *Id*.

## II. Legal Standard

### A. Introduction to the Doctrine of Primary Jurisdiction

The doctrine of primary jurisdiction is a judicially created doctrine that was first invoked by the United States Supreme Court at the beginning of the twentieth century. *See Tex. & Pac. Ry. v. Abilene Cotton Oil Co.*, 204 U.S. 426 (1907); *see also* Nicholas A. Lucchetti, Note, *One Hundred Years of the Doctrine of Primary Jurisdiction: But What Standard of Review is Appropriate for It?*, 59 Admin. L. Rev. 849, 854 (2007). "Under the doctrine of primary jurisdiction a court can refer a technical or factual issue to an administrative agency for expert determination." James W. Hilliard, *Tapping Agency Expertise: The Doctrine of Primary Jurisdiction*, 96 Ill. B.J. 256, 256 (2008). "The development of the primary jurisdiction doctrine is a function of the judiciary's recognition that the adjudicatory authority of regulatory agencies will inevitably overlap with the jurisdiction of traditional judicial courts." Paula K. Knippa,

Note, *Primary Jurisdiction Doctrine and the Circumforaneous Litigant*, 85 Tex. L. Rev. 1289, 1290 (2007). "The doctrine of primary jurisdiction, like the rule requiring exhaustion of administrative remedies, is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties." *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63 (1956).

**B. Historical Background**

The doctrine of primary jurisdiction was established in the landmark case of *Texas & Pacific Railway Company v. Abilene Cotton Oil Company.*, 204 U.S. 426 (1907). Louis L. Jaffe, *Primary Jurisdiction*, 77 Harv. L. Rev. 1037, 1042 (1964). In *Abilene Cotton Oil*, a shipper claimed that a published carrier rate was unreasonable and sued the carrier in a state court for the excess. *Tx. & Pac. Ry.*, 204 U.S. at 430. "The Supreme Court held that the action did not lie since the [Interstate Commerce Commission ("ICC")] alone was competent to determine whether the carrier rate was reasonable. Jaffee, *supra*, at 1042. Justice White, writing for the Court, determined that the Commerce Act was "intended to abolish preferences and discriminations by establishing a uniform published rate." *Id.* "If power existed in courts or juries to revise a published rate there could be no uniformity, and this 'would render the enforcement of the [A]ct impossible.'" *Id.* at 1042 (quoting *Abilene Cotton Oil Co.*, 204 U.S. at 441). Thus, the Court determined that the issue of reasonable freight rates should first be decided by the ICC in order to promote regulatory uniformity. *Abilene Cotton Oil Co.*, 204 U.S. at 448.

The Supreme Court's holding in *Abilene Cotton Oil* suggests that an agency should have primary jurisdiction whenever the agency's exclusive control would promote the uniform enforcement of a statute. As the Supreme Court has refined the doctrine, however, it has limited

the holding in *Abilene Cotton Oil*, and additional considerations have emerged in the Court's analysis. Michael Penney, Note, *Application of the Primary Jurisdiction Doctrine to Clean Air Act Citizen Suits*, 29 B.C. Envtl. Aff. L. Rev. 399, 403 (2002).

In *Great Northern Railway Company. v. Merchants' Elevator Company.*, 259 U.S. 285 (1922), the Supreme Court addressed, for the first time, agency expertise in the context of applying primary jurisdiction in a case involving statutory construction. Penney, *supra*, at 404. The case involved another railroad freight dispute. *Great N. Ry. Co.*, 259 U.S. at 288. Merchants' Elevator Company claimed that the railroad violated its government-approved rates and that a special statutory rule allowing the railroad to charge more under certain circumstances did not apply. *Id*. at 288–89. Thus, the complete issue revolved around the interpretation of a statutory provision, and the railroad argued that, under *Abilene Cotton Oil*, the Court should hold that the ICC had jurisdiction over the matter; but the Court disagreed. *Id*. at 290.

First, the Court in *Great Northern Railway Company* noted that issues involving statutory and rule construction are questions of law that courts generally have the capacity to address. *Id*. at 290–91. Second, the Court stated the appellate process could also ensure uniformity because, while issues of construction may arise in federal or state courts, appellate courts could review lower court decisions to ensure a uniform application of the law. *Id*. "The Supreme Court agreed that agency interpretations would promote uniformity, but the Court concluded that this did not automatically support a holding for primary jurisdiction in the agency because granting jurisdiction to the agency was not the *only* means to ensure uniform construction and application of statutes." Penney, *supra*, at 404. The Supreme Court established that the degree of agency

expertise needed to resolve the issue would determine how the Court should allocate jurisdiction. *See Great N. Ry. Co.*, 259 U.S. at 291.

The Supreme Court offered its most complete articulation of the primary jurisdiction doctrine in *Western Pacific Railroad Co.*, 352 U.S. 59 (1956). Knippa, *supra*, at 1297. The Court distinguished the doctrine from other, closely-related legal principles and emphasized the doctrine's two primary purposes: uniform regulation and reliance upon agency experts. *See W. Pac. R.R. Co.*, 352 U.S. at 64.

**C. Primary Jurisdiction Is Not Exhaustion of Remedies**

In *Western Pacific Railroad Company.*, the Supreme Court took care to distinguish the primary jurisdiction doctrine from the similar doctrine of exhaustion of administrative remedies: "'Exhaustion' applies where a claim is cognizable in the first instance by an administrative agency alone. . . . 'Primary jurisdiction,' on the other hand, applies where a claim is originally cognizable in the courts." *Id*. at 63–64. The doctrine "comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *Id*. at 64. Thus, "[i]f the issue is one 'that Congress has assigned to a specific agency,' the doctrine of primary jurisdiction allows the court to stay the judicial proceedings and direct the parties to seek a decision before the appropriate administrative agency." *S. Utah Wilderness All. v. Bureau of Land Mgmt.*, 425 F.3d 735, 750–51 (10th Cir. 2005) (citations omitted) (quoting *Williams Pipe Line Co. v. Empire Gas Corp.*, 76 F.3d 1491, 1496 (10th Cir. 1996)). "The agency is then said to have 'primary jurisdiction.'" *Id*. at 751.

The name "primary jurisdiction," however, is a misnomer because a court must first have subject matter jurisdiction for the doctrine to apply at all. Lucchetti, *supra*, at 853. The doctrine "applies where a claim can originally be addressed in a court but would be better addressed first by an administrative body." 2 Am. Jur. 2d Admin. L. § 456 (2015).

**D. When Courts Apply the Doctrine**

"There is no mechanical formula for applying the doctrine of primary jurisdiction." *S. Utah Wilderness All.*, 425 F.3d at 751. "In every case the question is whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its application in the particular litigation." *W. Pac. R.R. Co.*, 352 U.S. at 64.

In earlier cases, the Supreme Court emphasized the desirable *uniformity* that would come from a specialized agency initially deciding certain types of administrative questions. *Id*. at 64. More recently, the Supreme Court has focused of the expert and specialized knowledge of the agencies involved. *Id.* The Supreme Court applies a firmly established principle that "in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over." *Far E. Conf. v. United States*, 342 U.S. 570, 574 (1952). Conversely, "the doctrine of primary jurisdiction does not apply where the issue sought to be referred involves a question of law rather than a question of fact requiring technical expertise." Hilliard, *supra*, at 258.

**E. Agency Must Have Authority Over Relevant Issues**

A court's review of the purposes behind the doctrine of primary jurisdiction, of course, assumes that a specific agency actually *has* authority and expertise over the relevant issues. *S.*

*Utah Wilderness All.*, 425 F.3d at 751 ("All of this assumes that Congress has, by statute, given authority over the issue to an administrative agency."). Accordingly, before a court assesses whether the purposes underlying proper application of the doctrine are present in a particular case, the court must first determine the scope of authority an administrative agency possesses over the issues. *Id.*; *see also* 73 C.J.S. Pub. Admin. L. & Proc. § 114 (2015) ("[T]he court and the administrative agency must have concurrent jurisdiction over the dispute or a portion of it.") (footnote omitted).

**F. The Application of the Doctrine Cannot Be Waived**

A decision to apply the doctrine to a particular case is in the sound discretion of the court. *See Envtl. Tech. Council v. Sierra Club*, 98 F.3d 774, 789 (4th Cir. 1996) (reviewing for abuse of discretion the district court's decision not to refer a matter pursuant to the doctrine of primary jurisdiction). Further, "[t]he court may raise the issue of primary jurisdiction on its own initiative, and its invocation cannot be waived by the failure of the parties to argue it as the doctrine exists for the proper distribution of power between judicial and administrative bodies and not for the convenience of the parties." 2 Am. Jur. 2d Admin. L. § 456 (2015); *see also Red Lake Band Chippewa Indians v. Barlow*, 846 F.2d 474, 476 (8th Cir. 1988) ("We realize that neither party has raised the issue of primary jurisdiction up to this point. It is well established, however, that its invocation cannot be waived by the failure of the parties to argue it. . . ."). In other words, the court may invoke the doctrine sua sponte.

**G. Referring Issues: Staying Judicial Proceedings or Dismissing Without Prejudice**

The primary jurisdiction doctrine functions by allowing courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue before the relevant

administrative agency. 73 C.J.S. Pub. Admin. L. & Proc. § 120 (2015). Federal courts have recognized dismissal of the case without prejudice as a form of referral in applying the doctrine of primary jurisdiction. Hilliard, *supra*, at 259. The doctrine allows a "court to enable a 'referral' to the agency, staying further proceedings so as to give the parties reasonable opportunity to seek an administrative ruling." *Reiter v. Cooper*, 507 U.S. 258, 268 (1993).

A "referral"[3] to the agency does not cause a court to lose jurisdiction; the court may retain jurisdiction, or it may dismiss it without prejudice if dismissal will not unfairly disadvantage the parties. *Id*. at 268–69. A court should choose the approach that provides the parties a reasonable opportunity to seek an administrative ruling. *Id*. at 268. If dismissal of the suit would be prejudicial to one of the parties, it should be stayed. *See Far E. Conf.*, 342 U.S. at 577. "Dismissal of the complaint may be appropriate when the parties can obtain all of the relief that they seek in court in an administrative forum or in an easily initiated suit subsequent to the administrative proceedings." Hilliard, *supra*, at 259. "Where the referral is in the form of dismissal without prejudice, neither party is precluded from seeking judicial review of the administrative agency decision." *Id*.

If a district court dismisses an action without prejudice, a plaintiff must start over before the appropriate agency. Robert B. von Mehren, *The Antitrust Laws and Regulated Industries: The Doctrine of Primary Jurisdictio*n, 67 Harv. L. Rev. 929, 952 (1954). A plaintiff will do this usually by filing a complaint with the agency pursuant to the agency's regulations. *Id*. If the

[3] "'Referral' is sometimes loosely described as a process whereby a court refers an issue to an agency." *Reiter v. Cooper*, 507 U.S. at 268 n.3. "Use of the term 'referral' to describe this process seems to have originated in *Western Pacific*, which asserted that, where issues within the special competence of an agency arise, 'the judicial process is suspended pending referral of such issues to the administrative body for its views.'" *Id*. (quoting *W. Pac. R.R. Co.*, 352 U.S. at 64). "*Mitchell Coal* spelled out the actual procedure contemplated, holding that further action by the district court should 'be stayed so as to give the plaintiff a reasonable opportunity within which to apply to the Commission for a ruling as to the reasonableness of the practice." *Id*. (quoting *Mitchell Coal & Coke Co. v. Pa. R.R. Co.*, 230 U.S. 247, 267 (1913)).

proceedings are stayed, a plaintiff will seek an administrative review of the issues while the court retains jurisdiction. *Id*.

If a court chooses to retain jurisdiction over the case and stay the proceedings, it may employ any one of three types of referral: (1) it may do nothing beyond requiring the parties to apply to the administrative agency for a determination;[4] (2) it may request an amicus curiae brief from the administrative agency; [5] or (3) it may certify questions to the agency.[6] After an agency has resolved an issue within its purview, a court can then proceed to resolve the claim in a manner that is consistent with the agency's resolution.[7] 73 C.J.S. Pub. Admin. L. & Proc. § 120.

**III. Discussion**

Interestingly, the plaintiff completely avoids any discussion of the FDA, its regulations or statutory authority, or its control over medical device issues in her Brief on Primary Jurisdiction [ECF No. 30]. Even more, the plaintiff does not refer to any of the safety issues that so permeated the Complaint and Motion for a TRO and for a Preliminary Injunction. Instead, the plaintiff points out that her underlying Complaint, on its face, does not invoke the Federal Food, Drug, and Cosmetic Act ("FDCA"), but is a suit based on "continued misrepresentations and fraudulent conduct—namely, [Boston Scientific's] smuggling and sale of counterfeit, Chinese mesh that caused *economic injury*." Pl.'s Br. Primary Jurisdiction 4 (emphasis added). The plaintiff argues that applying the doctrine of primary jurisdiction will not promote national

[4] *See Bernhardt v. Pfizer, Inc.*, No. 00-cv-04042-LMM, 2000 WL 1738645 (S.D.N.Y. 2000); *see also Mitchell Coal & Coke Co.*, 230 U.S. at 267 (permitting the case to be stayed to give the plaintiff a reasonable opportunity to seek an administrative determination); Hilliard, *supra*, at 260.
[5] *See Cole v. U.S. Capital, Inc.*, 389 F.3d 719 (7th Cir. 2007).
[6] *See Phillips v. AWH Corp.*, 376 F.3d 1382 (Fed. Cir. 2004).
[7] Where the agency declines to provide guidance at all or in a timely manner, the court may proceed with the litigation without the guidance. *Owner-Operator Indep. Drivers Ass'n., Inc. v. New Prime, Inc.* 192 F.3d 778, 785 (8th Cir. 1999).

uniformity in the field of regulation, and the court will not benefit from agency expertise. *Id*. at 4–9. The court disagrees.

Initially, the FDCA did not regulate the marketing or approval of medical devices, but Congress authorized the FDA's control over the introduction of medical devices with the enactment of the Medical Device Amendments of 1976 ("MDA"). *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475–77 (1996); *see also* David T. Schultz & D. Scott Aberson, *Be Careful What You Ask For: The FDA's Denials of Citizen Petitions Confirms There is No Such Thing as a Limited Premarket Approval*, 39 Wm. Mitchell L. Rev. 1157, 1159–60 (2013) (stating that the MDA expanded the FDA's authority to regulate medical devices).

Under the MDA, a medical device may not be marketed without FDA approval or clearance based upon a statutory classification system. *See* 21 U.S.C. § 360c; *see also Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1168 (8th Cir. 1994) ("The MDA gives the [FDA] authority over medical devices and authorizes the FDA to issue implementing regulations."). Medical device manufacturers must register each device with the FDA before beginning manufacture. *Martello*, 42 F.3d at 1168. Devices may be cleared through the FDA's expedited 510(k) premarket notification process if the agency determines that the device is substantially equivalent to a pre-existing approved predicate device. *Lohr*, 518 U.S. at 477–79; *see also* Jeffrey Zigler, John Walsh, & Jack Zigler, *Medical Device Reporting: Issues with Class III Medical Devices*, 62 Food & Drug L.J. 573, 573 (2007) (stating that a manufacturer must demonstrate substantial equivalence to a predicate device that was on the market for the same intended use prior to the establishment of the MDA to justify 510(k) clearance).

Once a device is cleared pursuant to the FDA's 510(k) process, the FDA maintains authority over the manufacturer and the device itself. *See generally* 21 U.S.C. § 360j;[8] 21 U.S.C. § 334;[9] 21 U.S.C. § 351(h);[10] 21 U.S.C. § 374.[11] The FDCA, as amended by the MDA, "imposes a comprehensive set of requirements upon medical devices." *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010). For example, the FDA has explicit authority to require medical device manufacturers to (1) conduct post-market surveillance when their devices will be implanted in the human body for more than one year;[12] (2) follow certain labeling rules;[13] (3) report adverse events related to the use of the device, such as severe injury or death;[14] (4) report when the manufacturer removes a device from the market to reduce a risk to public health;[15] (5) recall a medical device;[16] and (6) adopt a method of tracking a device within the marketplace.[17]

The FDA's domain includes authority to prevent or ameliorate the introduction of adulterated or misbranded drugs and devices into the market. *See* 21 U.S.C. §§ 351–52. "Adulterated medical devices are liable to seizure and condemnation at any time" under the FDCA. *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves, An Article of Device*, 799 F. Supp. 1275, 1285 (D.P.R.1992) (citing 21 U.S.C. § 334(a)(2)(D)). A manufacturer has no right to conduct a business regulated by the FDCA in an unlawful manner. *United States v. Diapulse Corp. of Am.*, 457 F.2d 25, 29 (2d Cir.1972); *see also United States v.*

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[8] The statute establishes general provisions respecting control of devices intended for human use.
[9] The statute provides authority and a procedure for seizing medical devices.
[10] The statute declares a device adulterated if the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements or agency orders.
[11] The statute authorizes FDA inspections.
[12] 21 U.S.C. § 360*l*.
[13] 21 C.F.R. § 801.1, *et seq.*
[14] 21 C.F.R. § 803.1, *et seq.*
[15] 21 C.F.R. § 806.1, *et seq.*
[16] 21 C.F.R. § 810.1, *et seq.*
[17] 21 C.F.R. § 821.1, *et seq.*

*Ellis Res. Labs., Inc.*, 300 F.2d 550, 554 (7th Cir. 1962) (holding that a company can have no vested interest in a business activity found to be illegal). Further, the FDA has broad enforcement power under the FDCA, including the ability to initiate injunction proceedings,[18] seek penalties,[19] issue "debarments" and deny approval of future device applications,[20] and seek criminal prosecution.[21]

In arguing that the FDA has specialized knowledge over at least part of the issues presented in this case, Boston Scientific states "[t]he FDA is best suited to interpret its 510(k) authorization and to make the threshold scientific determinations necessary to do so." Def.'s Br. Primary Jurisdiction 6 [ECF No. 31]. Further, Boston Scientific argues that, "[n]ot only does the FDA have the peculiar expertise and authority to determine the merits of Plaintiff's essential allegations . . . the FDA has specific experience and expertise to fashion remedial measures as necessary." *Id*. at 7. The court agrees.[22]

The plaintiff asks this court to wield its equitable power to restrain Boston Scientific from marketing, selling, or importing its mesh devices containing the alleged counterfeit

[18] 21 U.S.C. § 332.
[19] 21 U.S.C. §§ 333, 335b.
[20] 21 U.S.C. § 335a.
[21] 21 U.S.C. § 336.
[22] While the FDA does have wide-ranging authority to prevent or ameliorate the introduction of adulterated, misbranded, and unauthorized devices into the market, the FDA does not have inherent authority to revoke or rescind clearance issued under its 510(k) process. *Ivy Sports Med., Inc. v. Burwell*, 767 F.3d 81 (D.C. Cir. 2014). In *Ivy Sports*, the FDA claimed that it was using its inherent regulatory power when it rescinded its substantial equivalence determination for a mesh device implanted after common knee surgeries in order to "rectify an error" in its review process. *Id*. at 85. The D.C. Circuit pointed out that "[t]he Act does not contain an express provision granting FDA authority to reconsider its substantial equivalence determinations," and it held that the FDA should have utilized its explicit statutory authority to reclassify the device. *Id*. at 86–87. The issue of revoking or rescinding a 510(k) clearance is not present here, however. As discussed *supra*, the plaintiff alleges that Boston Scientific's mesh device is, in fact, *not* cleared through the FDA's expedited process because, as she alleges, any Advantage mesh produced without authentic Marlex is not an FDA cleared device. *See* Compl. ¶ 10. Alternatively, the issue presented here could be viewed as one where a cleared device is simply in non-compliance with a previous FDA directive (i.e., the duty to be substantially equivalent to a predicate device). Both characterizations, however, certainly present situations where the FDA may act in the first instance pursuant to its broad regulatory authority over the medical device industry.

polypropylene resin. *See, e.g.*, Pl.'s Mot. TRO & Prelim. Inj. 2. As discussed *supra*, many of the factual allegations contained in the Complaint and supporting documents are based on alleged violations of statutes and regulations over which the FDA exercises its expertise and impressive administrative dominance. Congress established an extensive listing of prohibited acts under the FDCA when it enacted 21 U.S.C. § 331. Further, the MDA, which establishes the expedited 510(k) clearance process, is enforced by the FDA—necessitating many specialized scientific determinations. The FDA is in the best position to determine whether Boston Scientific's mesh device is in compliance with the FDA's own statutes, regulations, and directives—particularly because the FDA was the very agency that cleared Boston Scientific's mesh device in the first place. Accordingly, the court **FINDS** that the principle purposes underlying the application of the doctrine of primary jurisdiction are present here. Imposing the severe equitable relief that the plaintiff seeks would prevent the FDA from taking the first action in an area in which that agency clearly has expertise and an interest in the uniform application of its regulatory framework.

Lastly, there is a remedial administrative process at the plaintiff's disposal to address these important issues. Specifically, the FDA has provided a procedure by which private individuals may initiate an administrative proceeding to petition the FDA Commissioner to take administrative action. *See* 21 C.F.R. §§ 10.25, 10.30. In fact, the FDA, through its regulations, has squarely addressed its view of the doctrine of primary jurisdiction as it applies to its authority:

> [The] FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency

> or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination. The Commissioner may utilize any of the procedures established in this part in reviewing and making a determination on any matter initiated under this paragraph.

21 C.F.R. § 10.25(b). Additionally, the FDA regulations state that the FDA Commissioner will institute a proceeding to determine whether to take some form of administrative action whenever a court holds a case in abeyance for an administrative determination. 21 C.F.R. § 10.25(c). Accordingly, the court **FINDS** that the FDA's own regulations contemplate the application of the doctrine of primary jurisdiction and provide procedures to handle referrals when courts apply the doctrine to issues within the agency's statutory mandate.

The court notes that it does not presently have enough information to evaluate the prejudices or hardships, if any, the parties would suffer should the court dismiss this action without prejudice. The court further notes that the plaintiff would be unable to obtain complete relief with an FDA referral, as this case is brought under the RICO Act and West Virginia substantive law. Accordingly, this case is **STAYED** pending the plaintiff's application to the United States Food and Drug Administration for a determination specific to her allegations regarding Boston Scientific's mesh products. The court **RETAINS** jurisdiction over this case, and the plaintiff is **ORDERED** to file a status report with this court on or before May 1, 2016, regarding her effort to seek FDA consideration of these issues. Once the FDA has taken any action relevant to the plaintiff's allegations, the plaintiff is **ORDERED** to provide such information to the court within fourteen days of receipt. The plaintiff is responsible for providing the FDA with notice of this Memorandum Opinion and Order.

The **DIRECTS** the Clerk to retire the case to the court's inactive docket. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party and post a copy of this published opinion on the court's website, www.wvsd.uscourts.gov.

ENTER: January 26, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE